REMARKS

Claims 1, 3-7, 9-16, 18-23, 26-27, and 38-42 are pending in the application. Claims 1, 16, 38 and 39 have been amended and new claims 40-42 have been added. Support for the amendments to the claims and for the new claims can be found in the specification at, *e.g.*, page 12, line 3 to page 13, line 20; and original claims 1, 4, 6 and 16. No new matter is added.

Claim rejections

35 U.S.C. § 112, first paragraph

Enablement

Claims 1, 3-7, 9-16, 18-23, 26-27, 38 and 39 have been rejected for lack of enablement. The Examiner has acknowledged that the specification is enabling for "a method for identifying a substance that is likely to prevent or diminish a specific biological response in a subject...by observing in a test subject having an inflammatory disease-associated genotype comprising at least one inflammatory disease-associated allele from the IL-1 44112332 haplotype cluster or the IL-1 33221461 haplotype cluster, a biomarker ..." but is not enabling for "an allele selected from the group consisting of an IL-1A allele, and IL-1B allele, and IL-1RN allele, a TNF-A allele, and an IL-13 allele." (See, Office action at page 3.) Applicants have amended claims 1, 16, 38 and 39 to recite specific alleles comprising the 44112332 and 33221461 haplotypes. Applicants submit that these claims, as amended herein, are fully enabled by the specification as filed. Claims 3-7, 9-15, 18-23, and 26-27 each depends either directly or indirectly from claims 1 or 16, and as such necessarily contain all of the limitations of claims 1 or 16. Therefore, these claims are also enabled by the specification as filed.

Applicants request that this rejection be withdrawn.

New claim 40 is drawn to a subset of the alleles provided in claims 1 and 16, an IL-1B (-511) allele 2 and an IL-1B (-3954) allele 2. New claim 41, which depends from claim 40, recites that the inflammatory disease-associated genotype also includes IL-1RN (+2018) allele 2, an IL-1RN (VNTR) allele, IL-1A (+48485) allele 2, or IL-1A (-889) allele 2. Similarly, new claim 42 recites the presence of four alleles from the list of alleles of claims 1 and 16: an IL-1B (-511) allele, an IL-1RN (+2018) allele or an IL-1RN (VNTR) allele, an IL-1A (+4845) allele or an IL-1A (-889) allele, and an IL-1A (+3954) allele. As the Examiner has indicated that the use of

each of the alleles recited in new claims 40-42 are enabled by the originally filed specification, Applicant asserts that claims 40-42 meet the enablement requirement.

Written Description

Claims 1, 3-7, 9-16, 18-23, 26-27, 38 and 39 have also been rejected for lack of written description. The Examiner has stated that the claims as written encompass a large genus of nucleic acid sequences not adequately described or disclosed in the application in the recitation of "an allele selected from the group consisting of an IL-1A allele, and IL-1B allele, and IL-1RN allele, a TNF-A allele, and an IL-13 allele." (See, Office action at page 6.) The Examiner acknowledges that the specification discloses the identification of haplotypes that encompass allele 3 and allele 4 of the 222/223 marker of IL-1A, allele 3 and allele 4 of the gz5/gz6 marker of IL-1A, allele 1 and allele 2 of the +3954 marker of IL-1B, allele 1 and allele 2 of the -511 marker of IL-1B, allele 3 and allele 4 of the gaat.p333330 marker, allele 3 and allele 6 of the Y31 marker, allele 1 and allele 2 of the +2018 marker of IL-1RN, allele 1 and allele 2 of the +4845 allele of IL-1A, allele 1 and allele 2 of the VNTR marker of IL-1RN, and allele 2 of the +6912 marker of IL-1B. (Office action, pages 6-7.) Applicants note that while the Examiner has not included allele 1 and allele 2 of the -889 marker of IL-1A, these two alleles are contained within the 44112332 and 33221461 haplotypes provided on pages 12 and 13 of the specification, and Applicants therefore assert that the specification as filed disclosed these two alleles.

In order to advance prosecution, Applicants have amended claims 1, 16, 38 and 39 to specify that the at least one inflammatory disease associated allele is selected from the group of alleles acknowledged by the Examiner to have adequate written description. Therefore, Applicants assert that one skilled in the art would recognize that Applicants were in possession of the subject matter of amended claims 1, 16, 38 and 39. Claims 3-7, 9-15, 18-23, and 26-27 each depends either directly or indirectly from claims 1 or 16, and as such necessarily contain all of the limitations of claims 1 or 16. Thus, these claims are also adequately described. Applicants request that this rejection be withdrawn.

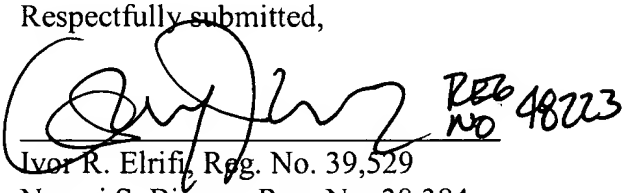
New claim 40 is drawn to a subset of the alleles provided in claims 1 and 16, an IL-1B (-511) allele 2 and an IL-1B (-3954) allele 2. New claim 41, which depends from claim 40, recites that the inflammatory disease-associated genotype also includes IL-1RN (+2018) allele 2, an IL-

1RN (VNTR) allele, IL-1A (+48485) allele 2, or IL-1A (-889) allele 2. Similarly, new claim 42 recites the presence of four alleles from the list of alleles of claims 1 and 16: an IL-1B (-511) allele, an IL-1RN (+2018) allele or an IL-1RN (VNTR) allele, an IL-1A (+4845) allele or an IL-1A (-889) allele, and an IL-1A (+3954) allele. As the Examiner has indicated that each of the alleles recited in new claims 40-42 are adequately described by the originally filed specification, Applicant asserts that claims 40-42 meet the written description requirement.

CONCLUSION

On the basis of the foregoing amendments, Applicants respectfully submit that the pending claims are in condition for allowance, and a Notice of Allowance is respectfully requested. If there are any questions regarding these amendments and remarks, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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